K052492

510 (k) Summary of safety and effectiveness

SEP - 5 2006

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Establishment registration number	3004139830
Name of contact	Dr. Martina Günderoth, MBA Eisenhutweg 15 84036 Kumhausen-Preisenberg, Germany Phone No.: ++49 871 430 8378 Fax No.: ++49 871 430 8379 E-mail: mguenderoth@onlinehome.de
Proprietary name	*AIRNERGY+®STREAM*
Common name	AIRNERGY STREAM
Classification name	Infrared lamp.
Code of Federal Regulations	21 CFR 890.5500
Regulatory Class	Class II
Device panel / product code	Physical medicine / ILY
Predicate device	There are several infrared lamps known in the market. One of these is the *Acubeam* of *Light Force Therapy, Inc.* (K 022888).
Description of device	Like the predicate devices the *AIRNERGY+® Stream* is a lamp that has the same indication for use and equivalent technology.

K052492

The device electrical and mechanical design is for use and convenience of the users. The red light is generated by LEDs (light emitting diodes) at a wave range between 600 and 650 nm.

Intended use

The AIRNERGY+® Stream is indicated for use to emit energy to provide topical heating for the purposes of elevating tissue temperature for temporary relief of minor muscle and joint pain, temporary relief of minor arthritis pain and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where applied.

Voluntary standard compliance

- IEC 60601-1
- IEC 60601-1-2

Tests have proven that the *AIRNERGY+®* is safe and effective with respect to its intended use and does not depict any risk to the user.

Conclusions

The *AIRNERGY+® Stream* is designed, labeled, and verified for performance and safety. Performance data has proven that it performes safe and effectively with respect to its intended use.
It conforms to applicable ISO standards.
It has the same indication for use and same technology as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Natural Energy Solutions AG
% C.R.C.
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Germany

SEP - 5 2006

Re: K052492
Trade/Device Name: ***AIRNERGY+***® STREAM
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: June 20, 2006
Received: June 27, 2006

Dear Dr. Gunderoth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052492

Device Name: ***AIRNERGY+®*** STREAM

Indications For Use:

The *AIRNERGY+® Stream* is indicated for use to emit energy to provide topical heating for the purposes of elevating tissue temperature for temporary relief of minor muscle and joint pain, temporary relief of minor arthritis pain and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where applied.

Prescription Use ____YES_ AND/OR Over-The-Counter Use _X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052494